

Remarks

Applicant thanks the Examiner for examining the present application. By this amendment, applicant is amending independent claim 36 to clarify certain features of the recited electrode and amending claims 44-48 and 71 to be more consistent with the amendment to independent claim 36. Support for these amendments can be found in the specification as filed at, for example, page 15, lines 25-28, page 16, lines 1-15, and page 17, lines 15-16. Applicant is additionally correcting a minor informality in claim 41. Applicant is also adding new claims 73-75, which are identical to original claim 36, previously presented claim 67, and previously presented claim 68, respectively. With entry of this amendment, claims 30-75 will be pending in the application, of which claims 30-35, 40, 59-66, and 72 are currently withdrawn.

The § 112 Rejections Should Be Withdrawn

The Examiner rejects claims 44-50 as being indefinite under 35 U.S.C. § 112, second paragraph. (Office action at pgs. 2 and 3.) The Examiner's rejection is traversed.

The Examiner first contends that claim 44 and claims 47-48 recite features that are not reconcilable. (Office action at pg. 2.) Although Applicant disagrees, claim 44 has been amended in view of the amendment to independent claim 36 and no longer recites the language objected to by the Examiner. Accordingly, the § 112 rejection of claims 44-48 should be withdrawn, and such action is respectfully requested.

The Examiner also contends that the "temporary lumen occluders" recited in claims 49 and 50 are not sufficiently disclosed in the specification. (Office action at pgs. 2 and 3.) Applicant disagrees.

The phrase "temporary lumen occluder" is clear and would easily be understood by one of ordinary skill in the art. Furthermore, examples of temporary lumen occluders are discussed in the specification as filed and would be recognizable as such by one of ordinary skill in the art. For instance, in the discussion of FIG. 4, the specification of the present application states: "To reduce [the] tendency to thrombosis during application of RF energy, a balloon 84 may be inflated in the vessel to occlude blood flow. Additionally, the entire segment can be isolated by inflation of proximal and distal balloons." (Specification, pg. 19, lines 4-7.)

Because one of ordinary skill in the art would have no trouble understanding the bounds of claims 49 and 50 in light of the specification as filed, the § 112 rejections of claims 49 and 50

should be withdrawn and such action is respectfully requested. (*See Howmedica Osteonics Corp. v. Tranquil Prospects, Ltd.*, 401 F.3d 1367 (Fed. Cir. 2005) (stating that the test for whether a claim meets the definiteness requirement is “whether one skilled in the art would understand the bounds of the claim when read in light of the specification.”))

Fleischman Does Not Teach Each and Every Element of Independent Claim 36

The Examiner rejects independent claim 36 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,545,193 (“*Fleischman*”). (Office action at pgs. 3-4.) The Examiner’s rejection is traversed.

At the outset, it is noted that the Examiner does not recite all elements of the claim in the Office action and does not expressly identify the portions of *Fleischman* believed to teach the elements of claim 36 as required by 37 C.F.R. § 1.104(c)(2). Instead, the Examiner recites only portions of independent claim 36 together with portions of dependent claims 38, 39, 41-48, 51, 53, 56, and 69-71. Without more, Applicant cannot determine the entire basis of the Examiner’s rejection. Accordingly, the Office action is not believed to be a proper action on the merits and any subsequent action should not be final. (*See* MPEP 706.07 and 706.07(a).) Applicant will nevertheless respond to the Examiner’s rejection as best as possible.

Fleischman describes several ablation probes having ablating elements that take the form of three-dimensional baskets. (*Fleischman*, col. 10, lines 46-49.) With respect to basket 92(4) in FIG. 12 (the structure relied on by the Examiner), *Fleischman* states that “each basket 92(1)/(2)/(3)/(4)/(5) comprises a base member 98 and an end cap 100. . . . [A]n array of generally resilient, longitudinal splines 102 extend in a circumferentially spaced relationship between the base member 98 and the end cap 100. They form the structure of the baskets 92(1)/(2)/(3)/(4)/(5).” (*Fleischman*, col. 15, lines 31-36.) “The splines 102 of each basket 92(1)/(2)/(3)/(4)/(5) also resiliently spring open to assume their three-dimensional shape when deployed in the atria 12/14.” (*Fleischman*, col. 15, lines 44-47.)

The Examiner apparently contends that FIG. 12B of *Fleischman* shows a “central spline” in the basket 92(4) that teaches the “movable core” recited in original claims 45 and 46. (Office action at pg. 3.) Applicant disagrees.

The spline referred to by the Examiner is labeled as a spline “102.” As noted above, *Fleischman* expressly states that “splines 102 . . . resiliently spring open to assume their three-

dimensional shape when deployed in the atria 12/14.” (*Fleischman*, col. 15, lines 44-47.) Accordingly, there is no central spline in FIG. 12B. The apparent central position of the spline 102 referenced by the Examiner is attributable to the angle at which the basket 92(4) is shown in FIG. 12B.

Further, the *Fleischman* reference is not believed to anywhere teach or suggest such a “central spline.” Instead, and as best illustrated by FIGS. 5A and 5B, the baskets 92(1)/(2)/(3)/(4)/(5) and baskets RA and LA disclosed in *Fleischman* comprise splines 102 that resiliently spring open to assume their three-dimensional shape when deployed in the atria and that only extend between the base member 98 and the end cap 100. (*Fleischman*, col. 11, lines 3-9; col. 15, lines 44-47). Neither the end cap 100 nor the splines 102 are attached to any central spline or electrode section that is substantially surrounded by another electrode section.

Accordingly, the cited sections of *Fleischman* do not teach or suggest an electrode comprising “a first section substantially surrounding a second section” and “two or more electrode struts attached to the second section at a distal approximation point and to the first section at a proximal approximation point” as in amended independent claim 36. For at least these same reasons, the cited sections of *Fleischman* also do not teach or suggest that “the first section and the second section are slidable relative to one another” as in amended independent claim 36.

For at least these reasons, *Fleischman* does not implicitly or expressly teach each and every element of independent claim 36 as required by 35 U.S.C. § 102(b). Accordingly, the Examiner’s § 102(b) rejection of claim 36 should be withdrawn and such action is respectfully requested. (See MPEP 2131 (“To anticipate a claim, the reference must teach every element of the claim.”).)

Dependent claims 38, 39, 41-48, 51, 53, 56, and 67-71 Are Also Allowable over *Fleischman*

The Examiner rejects dependent claims 38, 39, 41-48, 51, 53, 56, and 67-71 as being anticipated by *Fleischman*. (Office action at pgs. 3-4.) The Examiner’s rejections are traversed.

Claims 38, 39, 41-48, 51, 53, 56, and 67-71 are dependent on independent claim 36 and are allowable for at least the reasons stated above with respect to independent claim 36. Further, claims 38, 39, 41-48, 51, 53, 56, and 67-71 are each independently patentable because of the unique and nonobvious features of the combinations set forth in each claim. Accordingly, the

Examiner's rejections of claims 38, 39, 41-48, 51, 53, 56, and 67-71 should be withdrawn, and such action is respectfully requested.

With respect to claim 43, for example, the Examiner has not identified any portion of *Fleischman* that teaches or suggests that the "distal electrode end is detachable from the proximal electrode end upon delivery of a therapeutically effective amount of energy to the electrode." Instead, the Examiner cites a portion of *Fleischman* that recites that "the bridge splines 108 are soldered or otherwise fastened to the adjacent longitudinal splines 102." (Office action at pg. 2.) As seen in FIGS. 4A-B and 5A-B, however, the bridge splines 108 are small splines that interconnect adjacent longitudinal splines 102, and cannot be fairly construed as the "distal electrode end" of claim 43, which "substantially conforms to an inner surface of a hollow organ lumen of a subject" after being advanced through the distal catheter opening. Furthermore, there is no indication in *Fleischman* that the bridge splines 108 are "detachable . . . upon delivery of a therapeutically effective amount of energy to the electrode" as in claim 43.

With respect to claim 46, for example, *Fleischman* nowhere teaches or suggests that the second section of the electrode in claim 36 is "rotatable" relative to the first section.

With respect to claims 67 and 68, for example, the Examiner has not cited any portion of *Fleischman* that teaches or suggests that the source of radiofrequency energy is "capable of providing up to about 500 watts of radiofrequency energy to the electrode" as in claim 67 or "capable of providing up to about 200 watts of radiofrequency energy to the electrode" as in claim 68. Instead, the Examiner only contends that *Fleischman* teaches "an RF source capable of 30 watts." (Office action at pg. 3.) An RF source capable of 30 watts, however, does not teach a source of radiofrequency energy capable of providing up to about 500 watts of radiofrequency energy (as in claim 67) or up to about 200 watts of radiofrequency energy (as in claim 68).

Tu Does Not Teach Each and Every Element of Independent Claim 36

The Examiner rejects independent claim 36 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,036,689 ("*Tu*"). (Office action at pg. 4.) The Examiner's rejection is traversed.

At the outset, it is noted that the Examiner does not recite all elements of the claim in the Office action and does not expressly identify the portions of *Tu* believed to teach the elements of

claim 36 as required by 37 C.F.R. § 1.104(c)(2). Instead, the Examiner recites only portions of claim 36 together with portions of dependent claims 37, 38, 39, 44-48, 52, 54-58. Without more, Applicant cannot determine the entire basis of the Examiner's rejection. Accordingly, the Office action is not believed to be a proper action on the merits and any subsequent action should not be final. (*See* MPEP 706.07 and 706.07(a).) Applicant will nonetheless respond to the Examiner's concerns as best as possible.

Referring to FIGS. 3 and 4, *Tu* discloses “[an] electrode means 4 [] mounted at the distal end 25 of the inner catheter 21, wherein the electrode means 4 comprises a plurality of non-preshaped expandable metallic basket members 4A-4H or preshaped expandable metallic basket members 4I-4L, . . . wherein the basket proximal ends of the expandable metallic basket members are joined at the distal end 25 of the inner catheter 21 and wherein the basket distal ends of the expandable metallic basket members are joined at a distal joint 22.” (*Tu*, col. 5, lines 8-20.) *Tu* further states that “[a]n electrode deployment mechanism 17 is mounted on the handle 15, wherein the electrode deployment mechanism 17 is attached to the proximal end of the inner catheter 21.” (*Tu*, col. 5, lines 21-27.) *Tu* also discloses “a connecting shaft 23 [that] has a distal end and a proximal end, wherein the distal end of the connecting shaft 23 is joined to the distal joint 22 of the metallic basket members, and wherein the proximal end of the connecting shaft is secured to the electrode deployment mechanism 17.” (*Tu*, col. 5, lines 49-54.)

The Examiner apparently contends that the connecting shaft 23 of *Tu* is “advanceable and rotatable” relative to the inner catheter 21 because of the double-sided arrow shown in FIG. 4 of *Tu*. (Office action at pg. 4.) Applicant disagrees.

As noted above, *Tu* expressly teaches that “the proximal end of the connecting shaft [23] is secured to the electrode deployment mechanism 17.” (*Tu*, col. 5, lines 52-54.) *Tu* also expressly teaches that “the electrode deployment mechanism 17 is attached to the proximal end of the inner catheter 21.” (*Tu*, col. 5, lines 22-23.) Therefore, because the electrode deployment mechanism 17 is secured to the connecting shaft 23 and attached to the inner catheter 21, the connecting shaft 23 and the inner catheter 21 are understood to move together, not relative to one another.

Indeed, FIGS. 3 and 4 illustrate that the connecting shaft 23 and the inner catheter 21 of *Tu* move together when the electrode deployment mechanism 17 is operated. Specifically, FIG. 3 shows the distal end 25 of the inner catheter 21 and the electrode means 4 mounted at the distal

end 25 of the inner catheter 21 in a non-deployed state within the lumen 18 of the catheter shaft 11. FIG. 4 then shows the distal end 25 of the inner catheter 21 and the electrode means 4 mounted at the distal end 25 as they are advanced together out of the lumen 18 of the catheter shaft 11 with no apparent change in their relative positions. The double-sided arrow in FIG. 4 is consistent with the connecting shaft 23 and the inner catheter 21 moving together and does not teach or suggest any relative motion between the connecting shaft 23 and the inner catheter 21, especially in view of *Tu*'s express teaching against such relative motion.

Accordingly, the cited sections of *Tu* do not teach or suggest an electrode comprising "a first section substantially surrounding a second section, wherein the first section and the second section are slidable relative to one another" as in amended independent claim 36.

For at least these reasons, *Tu* does not implicitly or expressly teach each and every element of independent claim 36 as required by 35 U.S.C. § 102(e). Accordingly, the Examiner's § 102(e) rejection of claim 36 should be withdrawn and such action is respectfully requested. (*See* MPEP 2131 ("To anticipate a claim, the reference must teach every element of the claim.").)

Dependent claims 37-39, 41, 44-58, and 67-70 Are Also Allowable over *Tu*

The Examiner rejects dependent claims 37-39, 41, 44-58, and 67-70 as being anticipated by *Tu*. (Office action at pgs. 3-4.) The Examiner's rejections are traversed.

Claims 37-39, 41, 44-58, and 67-70 are dependent on independent claim 36 and are allowable for at least the reasons stated above with respect to independent claim 36. Further, claims 37-39, 41, 44-58, and 67-70 are each independently patentable because of the unique and nonobvious features of the combinations set forth in each claim. Accordingly, the Examiner's rejections of claims 37-39, 41, 44-58, and 67-70 should be withdrawn, and such action is respectfully requested.

With respect to claim 37, for example, the Examiner has not cited any portion of *Tu* that teaches or suggests that the "distal catheter opening comprises at least one side hole." Instead, the Examiner contends that the proximal end 35 of the wire guide lumen 36 in *Tu* teaches the "at least one side hole" of claim 37. Claim 35, from which claim 37 depends, clarifies that the recited electrode is capable of being "advanced through the distal catheter opening." Thus,

because the wire guide lumen 36 in *Tu* is not a lumen through which the electrode can be advanced, it cannot be the “at least one side hole” recited in dependent claim 37.

With respect to claim 46, for example, *Tu* nowhere teaches or suggests that the second section of the electrode in claim 36 is “rotatable” relative to the first section.

With respect to claim 54, for example, the Examiner has not identified any portion of *Tu* that teaches or suggests a method of using the device of claim 6 “wherein the method is a method of substantially occluding the lumen.” Instead, the Examiner refers to the abstract of *Tu*, which only recites an “ablation” device. Ablation, however, is a distinct operation that is substantially the opposite of occlusion. Accordingly, ablation cannot be fairly read to teach or suggest occlusion.

With respect to claims 67 through 70, for example, the Examiner has not cited any portion of *Tu* that teaches or suggests that the source of radiofrequency energy is “capable of providing up to about 500 watts of radiofrequency energy to the electrode” as in claim 67, “capable of providing up to about 200 watts of radiofrequency energy to the electrode” as in claim 68, “configured to provide between about 5 watts and about 200 watts of radiofrequency energy to the electrode” as in claim 69, or “configured to provide between about 20 watts and about 200 watts of radiofrequency energy to the electrode” as in claim 70.

New claims 73-75

New independent claim 73 is identical to original claim 36, and new dependent claims 74 and 75 are identical to claims 67 and 68.

In the rejection of original claim 36, the Examiner nowhere identifies any portion of *Fleischman* or *Tu* that teaches or suggests “a source of radiofrequency energy electrically connected to the electrode and capable of delivering a therapeutically effective amount of radiofrequency energy to the electrode that is capable of substantially occluding the lumen” as in new claim 73 (and original claim 36).

Fleischman is understood to teach only “ablation” devices and nowhere mentions “occlusion” or “occluding” a lumen of a hollow organ. *Tu* is also understood to teach only “ablation” devices and nowhere mentions “occlusion” or “occluding” a lumen of a hollow organ. Ablation and occlusion are distinct and substantially opposite operations. Consequently, the *Fleischman* and *Tu* devices do not teach or suggest “a source of radiofrequency energy

electrically connected to the electrode and capable of delivering a therapeutically effective amount of radiofrequency energy to the electrode that is capable of substantially occluding the lumen” as in claim 73.


New claims 73-75 are therefore believed to be in condition for allowance and such action is respectfully requested.

Conclusion

With entry of this amendment, the application is believed to be in condition for allowance and such action is respectfully requested. If there are any issues that remain concerning this matter, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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